

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *ex rel.*
DAVID M. KESTER, *et al.*

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS
CORPORATION, *et al.*

Defendants.

11 Civ. 8196 (CM)

**NOVARTIS PHARMACEUTICALS CORPORATION'S REPLY MEMORANDUM OF
LAW IN SUPPORT OF ITS MOTION TO DISMISS THE SECOND AMENDED
COMPLAINT OF RELATOR DAVID M. KESTER**

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Defendant Novartis Pharmaceuticals Corporation (“NPC”) submits this Reply Memorandum of Law in further support of its motion to dismiss, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Relator’s Second Amended Complaint (“Relator’s Complaint” or “SAC”).

PRELIMINARY STATEMENT

Relator devotes most of his opposition brief to attempting to persuade the Court that allegations of a kickback scheme render false “all claims” for a relevant medication that were “billed by a specialty pharmacy” to any government health care program during the pendency of the scheme, as Relator contends in his complaint. (*See* SAC ¶ 128.) Relator is wrong for the reasons set forth in NPC’s Motion to Dismiss the U.S. Government’s Amended Complaint, and in its Reply to the United States’ Opposition (the “Reply to the U.S.”), both of which NPC incorporates by reference herein.

Relator relegates the remainder of his opposition brief to mischaracterizing and misconstruing, and in some instances simply conceding, NPC’s arguments specifically relating to Relator’s Complaint. First, by mischaracterizing NPC’s challenge to the sufficiency of his conspiracy claims as an improper request for reconsideration, Relator dodges NPC’s argument that the weight of the case law—case law Relator fails to address—requires an underlying substantive violation of the FCA to state a claim for conspiracy. Second, Relator again mischaracterizes NPC’s argument that the United States’ FCA claims as to Myfortic supersede and compel dismissal of his own, as attacking his ability to participate in or recover from the pursuit of those claims. That is not what NPC argued, and Relator fails to address NPC’s actual argument that his claim has been superseded and should be dismissed. Finally, Relator concedes that several of his state FCA claims are overbroad in temporal scope.

ARGUMENT

I. RELATOR’S COMPLAINT SHOULD BE DISMISSED BECAUSE HE FAILS TO ALLEGE THAT ANY CLAIMS SUBMITTED FOR EXJADE, MYFORTIC, GLEEVEC, TASIGNA, OR TOBI RESULTED FROM NPC’S PURPORTED KICKBACKS.

As set forth in the Reply to the U.S., a plaintiff—whether the government or a relator—cannot state a claim under the FCA premised on an AKS violation without alleging a sufficient causal nexus between the alleged kickbacks and false claims submitted to the government for reimbursement.

Specific to this motion, however, Relator seeks to shield his claims for conspiracy to violate the federal and state FCAs from challenge by erroneously portraying NPC’s arguments regarding these claims as an improper request for reconsideration. *Novartis II* considered Rule 9(b) challenges to the sufficiency of Relator’s pleading. In the present motion, NPC argues under Rule 12(b)(6) that Relator’s conspiracy allegations cannot stand absent an adequately pled agreement to commit a substantive violation of the FCA. (*See Br.* at 5-6.)

Relator fails to address any of the half dozen court of appeals and district court cases cited by NPC in its motion that support this argument. (*See Br.* at 4-6.) In the face of this authority, Relator cites two out-of-circuit cases. (*Opp.* at 16-17). Neither case allowed a plaintiff to proceed with an FCA conspiracy claim in the absence of an underlying substantive violation of the FCA. Although the courts in those cases stated that no underlying substantive violation was required for an FCA conspiracy claim, they found that the complaints sufficiently alleged an underlying substantive violation of the FCA. *See U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 191-93 (5th Cir. 2009) (allowing conspiracy claims to proceed where court reinstated previously-dismissed substantive FCA claims); *U.S. v. St. Luke’s Subacute Hosp. & Nursing Centre, Inc.*, No. C 00–1976 MHP, 2004 WL 2905237, at *5-6 (N.D. Cal. Dec. 16,

2004) (allowing conspiracy claims to proceed where court simultaneously granted plaintiff's motion for summary judgment on substantive FCA claims).

The Court has already found that Relator has failed to plead an underlying substantive violation with respect to Gleevec, Tasigna, and TOBI, *see Novartis II* at 16, and therefore Relator's conspiracy claims with respect to these medications should be dismissed. Similarly, if NPC prevails on its argument that there must be some causal nexus between an alleged kickback and the false claims to state a substantive violation of the FCA, Relator's conspiracy claims should be dismissed with respect to Myfortic and Exjade as well.

II. RELATOR'S FEDERAL MYFORTIC CLAIMS SHOULD BE DISMISSED.

In an attempt to defeat NPC's straightforward and well-supported argument that the United States' complete intervention with respect to Relator's federal FCA claim as it relates to Myfortic requires dismissal of Relator's duplicative allegations (Br. at 6-7), Relator misconstrues both NPC's argument and the authority it cites in support: NPC is *not* attempting to deny Relator "the statutory right to participate in the litigation of his claims or the right to recover a relator share based on such claims" as Relator contends. (Opp. at 19-20.) Indeed, Relator acknowledges that NPC has not requested such a result. (*See id.* at 19 ("Such a result plainly would be an unjust consequence . . . and no defendant has even tried to argue to the contrary." (emphasis added)).) Rather, NPC is arguing that the U.S. Complaint is the operative pleading on those claims for which it has chosen to intervene, and, as a result, the Relator's redundant federal FCA claim as it relates to Myfortic should be dismissed.

The cases cited by Relator, which stand for the uncontroversial principle that a relator may still participate in litigation once the government has intervened, do not support maintaining the Relator's complaint for duplicative claims. *See U.S. ex rel. Landis v. Tailwind Sports Corp.*, No. 10-cv-00976 (RLW), 2014 WL 2772907, at *7 (D.D.C. June 19, 2014) (court was

addressing “challenges to the relator’s participation in this litigation”); *U.S. ex rel. Wilkins v. N. Am. Constr. Corp.*, 173 F. Supp. 2d 601, 644-45 (S.D. Tex. 2001) (mentioning dismissal but addressing only the relator’s continued participation in the litigation), *overruled on other grounds by U.S. ex rel. Longhi v. United States*, 575 F.3d 458 (5th Cir. 2009); *U.S. ex rel. Long v. SCS Bus. & Tech. Inst., Inc.*, 173 F.3d 870, 885 (D.C. Cir. 1999) (“The relator appears to remain a party whether or not the United States intervenes.”). Similarly, the statutory provisions governing a relator’s continued participation in litigation following government intervention cited by Relator do not address dismissal of duplicative claims. *See* 31 U.S.C. § 3730(c) (describing relator’s right to continue to participate as a party, subject to limitations).

Relator’s attempt to portray the authorities cited by NPC as supporting his position (Opp. at 19) because they address a relator’s right of participation in addition to the principle for which NPC actually cited them—that duplicative claims should be dismissed—is unremarkable for the same reason: NPC is not challenging Relator’s rights of participation. Relator fails to address the relevant teachings of these authorities. For example, in declining to dismiss a relator’s complaint where the government’s intervention was only partial, the court in *United States ex rel. Allen v. Guidant Corp.*, No. 11–22 (DWF/AJB), 2012 WL 878023 (D. Minn. Mar. 14, 2012) was careful to note that there was no overlap between the relator’s claims and the intervened claims. *See id.* at *7 (“In this case, Relator’s complaint pertains to defective Prizm 1861 devices manufactured *after* April 16, 2002. The government’s allegations with respect to the Prizm 1861 relate only to devices manufactured *before* April 16, 2002.”) (citations omitted). Had there been any degree of overlap between the relator’s claims and government’s claims in intervention, the court would have been required to dismiss the relator’s duplicative claims for lack of standing. *See id.* at *6 (“[I]f the Government only partially intervenes in an action, a relator may retain

standing to prosecute those aspects of his or her complaint *as to which the Government has not intervened.*” (emphasis added)). Here, although the United States has only partially intervened, its intervention has fully eclipsed the Relator’s federal FCA claim as it relates to Myfortic (*see* Br. at 7), and Relator does not contend otherwise.

Confronted by authority that plainly refutes his argument that his duplicative claims must be permitted to stand notwithstanding the United States’ intervention, Relator urges the court to simply ignore the authorities he cannot distinguish, but provides no compelling reason the Court should do so. For example, Relator contends that *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641 (S.D.N.Y. 2011) “does not cite authority for its ‘standing’ analysis.” (Opp. at 20.) To the contrary, *Feldman* cites numerous supporting authorities. *See Feldman*, 808 F. Supp. 2d at 648-49 (citing *U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 748 (9th Cir.1993); *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4287572, at *4 (D.Mass. Dec. 6, 2007); *U.S. ex rel. O’Keefe v. McDonnell Douglas Corp.*, 918 F. Supp. 1338, 1346 (E.D.Mo.1996)).

Relator also dismisses the *Badr* case as involving “what may be dicta.” (Opp. at 20.) In *Badr*, the court dismissed a relator’s complaint as superseded by the government’s complaint and dismissed the government’s complaint for failure to state a claim. *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 950 F. Supp. 2d 888, 895 & n.1 (E.D. Va. 2013). Even assuming that the government’s failure to state a claim was an additional basis for dismissing the relator’s complaint in *Badr*, alternate grounds for dismissal do not render the court’s stated grounds for dismissal “dicta” and, in any event, the inclusion of dicta would not make the court’s analysis incorrect. *See Ortiz v. Pearson*, 88 F. Supp. 2d 151, 165 (S.D.N.Y. 2000) (noting that even if a prior decision’s analysis was dicta, “it is persuasive dicta”).

Finally, Relator seeks but does not find salvation in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000). (See Opp. at 20.) *Stevens* does not address dismissal of duplicative relator claims, but merely holds that the United States' injury-in-fact is sufficient to confer standing on a relator to bring an FCA suit. See *Stevens*, 529 U.S. at 773-74. Although Relator attempts to seize on the reference in *Stevens* to relator "standing" to undermine *Feldman*, his reach exceeds his grasp: the "standing" discussed in *Stevens* as conferring a right of participation is not the same "standing" at issue in *Feldman* or pertinent to NPC's argument. Although a lack of standing ordinarily means that a party cannot participate in litigation, see, e.g., *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 475-76 (1982) ("Those who do not possess Art. III standing may not litigate as suitors in the courts of the United States."), NPC does not contend and *Feldman* does not hold that a relator's lack of standing to maintain a separate complaint on duplicative claims prohibits his continued participation in the United States' litigation of those claims. See, e.g., *Feldman*, 808 F. Supp. 2d at 649 ("The Court concludes that Feldman's Amended Complaint is superseded in its entirety by the Government's Amended Complaint and therefore dismisses Feldman's Amended Complaint for want of standing. The Court notes, however, that this dismissal in no way diminishes Feldman's continuing statutory rights delineated in § 3730 of the FCA . . ."). NPC respectfully submits that Relator is entitled to no different standard or result than the relator in *Feldman* and his duplicative claim based on alleged violations of the federal FCA with respect to Myfortic should be dismissed.

III. KESTER'S STATE LAW CLAIMS SHOULD BE DISMISSED WITH RESPECT TO CERTAIN TIME PERIODS.

As an initial matter, Relator concedes that he may not seek retroactive application of the FCAs of Connecticut, Minnesota, or Rhode Island or pursue claims on behalf of the State of

Texas for conduct prior to May 4, 2007. As a result, Relator's claims on behalf of Connecticut for conduct prior to October 5, 2009, on behalf of Minnesota for conduct prior to July 1, 2010, on behalf of Rhode Island for conduct prior to July 1, 2007, and on behalf of Texas for conduct prior to May 4, 2007 should be dismissed.

Relator also incorporates by reference the arguments made by various Intervening States in the Multistate Opposition to NPC's motion to dismiss various claims in their complaints. Given that the States of New Jersey, Georgia, and Oklahoma all concede that their FCAs do not apply retroactively, Relator's claims on behalf of New Jersey for conduct prior to March 13, 2008, on behalf of Georgia for conduct prior to May 24, 2007, and on behalf of Oklahoma for conduct prior to May 1, 2007 should also be summarily dismissed. With respect to the States' argument that the FCAs of Wisconsin, Maryland, and New York may applied retroactively, NPC incorporates by reference its response as set forth in its Reply to the Multistate Opposition, which demonstrates that the New York FCA is not retroactive and that, in any event, the retroactive application of the FCAs in these three states would be an unconstitutional violation the Ex Post Facto Clause. Accordingly, Relator's claims on behalf of Wisconsin for conduct prior to October 27, 2007, on behalf of Maryland for conduct prior to October 1, 2010, and on behalf of New York for conduct prior to April 1, 2007 should be dismissed.

Finally, Relator argues that his claims on behalf of New Mexico for conduct prior to November 14, 2007 should not be dismissed based on New Mexico's four-year statute of limitations because the statute of limitations for claims pursuant to New Mexico's FCA is subject to a discovery rule. Relator cites no authority to support his contention, and NPC has not identified a single instance where a New Mexico court applied the discovery rule to toll the statute of limitations for a cause of action under the New Mexico FCA. In the absence of such

authority, NPC respectfully submits that the Court should decline to extend the New Mexico FCA's statute of limitations and should dismiss Relator's claims on behalf of New Mexico for any alleged false claims submitted prior to November 14, 2007.

IV. NPC INCORPORATES BY REFERENCE ITS REPLY ARGUMENTS REGARDING LEGAL FALSITY.

Finally, Relator incorporates by reference the United States' arguments regarding legal falsity and his own arguments in opposition to the specialty pharmacies' motions to dismiss. NPC addresses legal falsity in its Reply to the U.S., and incorporates by reference those arguments herein.

CONCLUSION

For the foregoing reasons, as well as the reasons set forth in NPC's opening memorandum and the reasons set forth in NPC's initial motion to dismiss the U.S. Complaint and the Reply to the U.S., the Court should dismiss Relator's Complaint in its entirety.

Dated: July 3, 2014

Respectfully submitted,

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